

Remarks

This application has been subjected to five Office Actions, and a review is believed to be helpful.

In the first Office Action, dated December 23, 2005, the Office rejected the claims over a reference that did not qualify as prior art. This was clear error.

In the second Office Action, dated November 16, 2006, the Office again rejected the claims over the same reference cited in the first Action, which again did not qualify as prior art, thus repeating the clear error.

In the third Office Action, dated October 17, 2007, the Applicants were advised that all previous rejections were overcome. A double-patenting rejection was newly made, to which the Applicants responded by submitting a Terminal Disclaimer over not only the cited patent, but also (and voluntarily) over another related commonly-owned patent. No other rejections outstanding, the case was ready for allowance.

A fourth Office Action, dated July 29, 2008, followed, in which a Section 112 rejection was newly applied to claims that were pending before the second Office Action. But for the Section 112 rejection, the Office expressly indicated allowable subject matter in the remaining claims. In response, the Applicants accepted the allowable subject matter and responded to the Section 112 rejection by canceling the rejected claims. Once again, no other rejections outstanding, the case was ready for allowance.

A fifth Office Action, dated May 4, 2009, has now issued, in which newly cited art is applied, and to which the present response is directed.

As a first matter, the Applicants kindly remind the Office of its obligations under MPEP §707(g), that, "Piecemeal examination should be avoided as much as possible." As a second matter, if in response to the present amendment the Office were to contemplate a sixth Office Action, the Applicants kindly request a personal interview in advance of same.

Amendments to the Claims

Claim 13 has been amended to correct the antecedent basis and to further limit the treating. Support is believed to be found at, for example, specification page 21, line 4, to page 22, line 4.

Claim 23 has been amended to correct a minor omission. Support is found at, for example, specification pages 5 and 6, and specification page 16, lines 5-14.

No new matter is believed to be added. Upon entry of the amendments, Claims 11, 13-18, and 21-33 will be pending and in condition for allowance.

Rejection Under 35 U.S.C. 112, 2nd Paragraph

The Applicants acknowledge the rejection of claim 13 for insufficient antecedent basis. The rejection is obviated by amendment. The objectionable phrase has been removed from the claim, and the claim has otherwise been amended such that this ground of rejection is no longer tenable.

Rejection Under 35 U.S.C. 103

The Applicants acknowledge the rejection of claims 11, 13-18, and 21-33 over Bianchi et al. (JEM March 1996), Bukrinsky et al. (U.S. Patent No. 5,574,040) and Otto (U.S. Patent No. 5,616,578). The rejection is traversed.

The Office points out the correlation observed in Bianchi et al. that CNI-1493 attenuates TNF production and that TNF overproduction is observed in patients infected with HIV. There is nothing in the reference that elevates the correlation to *causation*, however. The Office correctly points out that Bianchi et al. do not state that CNI-1493 treats HIV. The reference discloses only that “proinflammatory cytokines, nitric oxide, and other macrophage products mediate the injurious sequelae that define a spectrum of diseases lethal septic shock, tissue injury, cachexia, hemorrhagic shock, vascular leakage syndromes, transplant rejection, rheumatoid arthritis, and other inflammatory states.” (Bianchi et al. page 927, left-hand

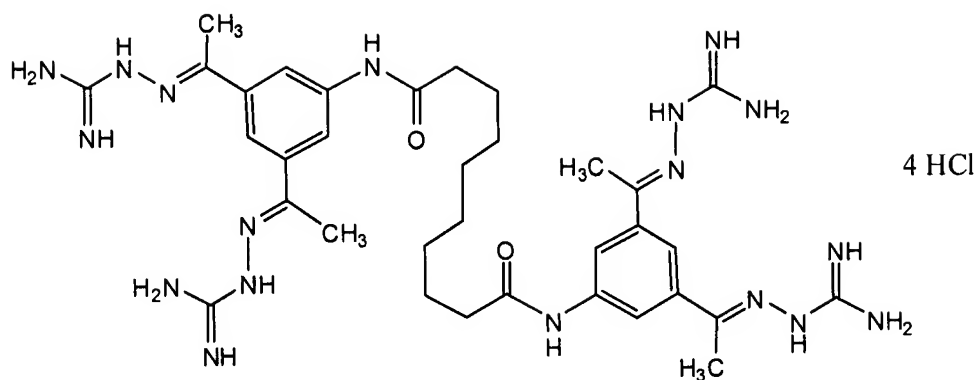
column). Bianchi et al. do not state that TNF either causes or mediates HIV. Mere correlation is not the same as causation, and the rejection cannot be sustained on this basis.

Regarding an ‘obvious to try’ rationale, the court in KSR¹ that a claim *might* have been obvious where one skilled in the art is choosing from “a finite number of identifiable, predictable solutions, with a reasonable expectation of success.” The Applicants kindly submit that the mere correlation observed in Bianchi et al. presents neither an indentifiable, predictable solution nor a reasonable expectation of success. Of the several disease states disclosed in Bianchi et al. as mediated by proinflammatory cytokines, HIV is not among them. Bianchi et al. also does not equate overproduction with mediation of all disease states. Further, Bianchi et al. state that the molecular target of the guanylylhydrazone compounds (e.g., CNI-1493) was not determined (Bianchi et al. page 934, right-hand column). As such, the Applicants submit that *prima facie* obviousness has not been established over the teachings of Bianchi et al.

The secondary references to Bukrinsky et al. and Otto are relied upon only for their disclosures of additional agents for the treatment of HIV to reject the dependent claims. The secondary references do not cure the deficiencies of the Bianchi et al. reference. As such, *prima facie* obviousness has not been established over the combination of references. The Applicants kindly request that the rejection be withdrawn.

The Office asserts that CNI-1493 reads on the compounds of Claims 21-25. For convenience, the structure of CNI-1493 is provided below:

¹ KSR International Co. v. Teleflex Inc., 550 U.S. 398, ___, 82 USPQ2d 1385, 1397 (2007).



CNI-1493

The Office states that CNI-1493 reads on claims 21-25. The Applicants kindly point out that while claims 21 and 25 are sufficiently broad to include CNI-1493, claims 22-24 are not so broad as to include CNI-1493. As such, it would be error to maintain the rejection of claims 22-24 over CNI-1493.

For all the reasons given above, and in view of the claim amendments, the Applicants kindly request Examiner Jagoe to withdraw the rejections and send this case to allowance. Should the Examiner have any questions regarding the application, or have any suggestions to place it into even better condition for allowance, she is kindly invited to telephone the Applicants' undersigned representative at the number below.

Respectfully submitted,

LAW OFFICE OF JOHN K. PIKE, PLLC

John K. Pike, Ph.D.
Registration No. 41,253

2121 Eisenhower Avenue, Suite 200
Alexandria, Virginia 22314
703.299.9450 v
703.299.9452 f